

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Page: 193  
Report Date:11/17/2008

**Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
<b>Male</b>							
Battelle Columbus Laboratory	058813803	08/16/99	729	50 (3)	22(681)	501.7	Benzophenone
Southern Research Institute	059902703	08/12/02	729	50 (3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50 (3)	33(703)	510.0	Cresols
Southern Research Institute	059900705	04/21/03	729	50 (3)	33(679)	460.9	Goldenseal root powder
Southern Research Institute	059201305	01/20/00	730	50 (3)	31(702)	448.0	4-Methylimidazole
Southern Research Institute	052000803	03/04/03	729	50 (3)	36(704)	452.1	Milk thistle extract
<b>Female</b>							
Battelle Columbus Laboratory	058813803	08/17/99	729	50 (5)	32(688)	348.7	Benzophenone
Southern Research Institute	059902703	08/12/02	733	50 (5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0 (0)	0(0)	N/A	Cresols
Southern Research Institute	059900705	04/21/03	731	50 (5)	30(699)	326.0	Goldenseal root powder
Southern Research Institute	059201305	01/20/00	735	50 (5)	40(702)	311.3	4-Methylimidazole
Southern Research Institute	052000803	03/04/03	732	50 (5)	38(693)	328.4	Milk thistle extract

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

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**Route: ORAL**  
**Vehicle: FEED**

**Page: 194**  
**Report Date:**11/17/2008

		Male						Female						
#All Organs:														
Benign Tumors														
		49/50	(98%)	49/50	(98%)	50/50	(100%)		42/50	(84%)	45/50	(90%)		
		47/50	(94%)	50/50	(100%)	50/50	(100%)		46/50	(92%)	48/50	(96%)	39/50	(78%)
Overall Incidence	Total	295/300 (98.33%)		Mean 98.33%		SD 2.34%		Total	220/250 (88%)		Mean 88%		SD 7.07%	
.....														
#All Organs:														
Malignant Tumors														
		33/50	(66%)	27/50	(54%)	23/50	(46%)		20/50	(40%)	15/50	(30%)		
		29/50	(58%)	22/50	(44%)	26/50	(52%)		19/50	(38%)	19/50	(38%)	18/50	(36%)
Overall Incidence	Total	160/300 (53.33%)		Mean 53.33%		SD 8.07%		Total	91/250 (36.4%)		Mean 36.4%		SD 3.85%	
.....														
#All Organs:														
Malignant and Benign Tumors														
		50/50	(100%)	50/50	(100%)	50/50	(100%)		46/50	(92%)	47/50	(94%)		
		50/50	(100%)	50/50	(100%)	50/50	(100%)		48/50	(96%)	48/50	(96%)	46/50	(92%)
Overall Incidence	Total	300/300 (100%)		Mean 100%		SD 0%		Total	235/250 (94%)		Mean 94%		SD 2%	
.....														
#All Organs:														
Hemangioma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/300 (0.33%)		Mean 0.33%		SD 0.82%		Total	0/250 (0%)		Mean 0%		SD 0%	
.....														
#All Organs:														
Hemangiosarcoma														
		0/50	(0%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/300 (0.67%)		Mean 0.67%		SD 1.63%		Total	0/250 (0%)		Mean 0%		SD 0%	

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

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Species: RATS  
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Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 195**  
**Report Date: 11/17/2008**

		Male						Female						
#All Organs: Hemangiosarcoma or Hemangioma														
		0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total	0/250	(0%)	Mean	0%	SD	0%
.....														
#All Organs: Histiocytic Sarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	3/50	(6%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	2.45%	Total	4/250	(1.6%)	Mean	1.6%	SD	1.67%
.....														
#All Organs: Leukemia: Erythrocytic														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%
.....														
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated														
		27/50	(54%)	19/50	(38%)	15/50	(30%)	19/50	(38%)	9/50	(18%)	6/50	(12%)	
		21/50	(42%)	15/50	(30%)	17/50	(34%)	9/50	(18%)	9/50	(18%)	6/50	(12%)	
Overall Incidence	Total	114/300	(38%)	Mean	38%	SD	9.12%	Total	52/250	(20.8%)	Mean	20.8%	SD	9.96%
.....														
#All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type														
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

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Species: RATS  
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Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 196**  
**Report Date: 11/17/2008**

Male														Female					
#All Organs:																			
Mesothelioma: Benign																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#All Organs:																			
Mesothelioma: Benign, Malignant, NOS																			
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#All Organs:																			
Mesothelioma: Malignant																			
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#All Organs:																			
Osteoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#All Organs:																			
Osteosarcoma																			
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

Male										Female					
#All Organs:															
Osteosarcoma or Osteoma															
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)	1/50	(2%)			0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	4/300	(1.33%)	Mean	1.33%	SD	1.63%	Total		1/250	(0.4%)	Mean	0.4%	SD	0.89%
*Adrenal Cortex:															
Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	2/50	(4%)		
		0/50	(0%)	1/50	(2%)	2/50	(4%)			1/50	(2%)	1/49	(2%)	0/48	(0%)
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total		4/247	(1.62%)	Mean	1.61%	SD	1.68%
*Adrenal Cortex:															
Carcinoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/49	(0%)	0/48	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/247	(0%)	Mean	0%	SD	0%
*Adrenal Medulla:															
Ganglioneuroma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/48	(0%)	0/48	(0%)	0/48	(0%)
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%	Total		0/244	(0%)	Mean	0%	SD	0%
*Adrenal Medulla:															
Hemangioma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/48	(0%)	0/48	(0%)	0/48	(0%)
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%	Total		0/244	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

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 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 198**  
**Report Date: 11/17/2008**

Male														Female					
*Adrenal Medulla: Pheochromocytoma Benign																			
		8/50	(16%)	8/50	(16%)	8/50	(16%)		0/50	(0%)	1/50	(2%)							
		5/49	(10%)	8/50	(16%)	5/50	(10%)		0/48	(0%)	2/48	(4%)	1/48	(2%)					
Overall Incidence	Total	42/299	(14.05%)	Mean	14.03%	SD	3.05%	Total	4/244	(1.64%)	Mean	1.65%	SD	1.74%					
.....																			
*Adrenal Medulla: Pheochromocytoma Complex																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/49	(0%)	2/50	(4%)	1/50	(2%)		0/48	(0%)	0/48	(0%)	1/48	(2%)					
Overall Incidence	Total	3/299	(1%)	Mean	1%	SD	1.67%	Total	1/244	(0.41%)	Mean	0.42%	SD	0.93%					
.....																			
*Adrenal Medulla: Pheochromocytoma Malignant																			
		0/50	(0%)	3/50	(6%)	0/50	(0%)		0/50	(0%)	2/50	(4%)							
		1/49	(2%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	1/48	(2%)	0/48	(0%)					
Overall Incidence	Total	4/299	(1.34%)	Mean	1.34%	SD	2.42%	Total	3/244	(1.23%)	Mean	1.22%	SD	1.8%					
.....																			
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS																			
		8/50	(16%)	11/50	(22%)	8/50	(16%)		0/50	(0%)	3/50	(6%)							
		6/49	(12%)	10/50	(20%)	6/50	(12%)		0/48	(0%)	3/48	(6%)	2/48	(4%)					
Overall Incidence	Total	49/299	(16.39%)	Mean	16.37%	SD	4.03%	Total	8/244	(3.28%)	Mean	3.28%	SD	3.1%					
.....																			
#Bone: Chondrosarcoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

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 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 199**  
**Report Date: 11/17/2008**

Male														Female					
#Bone: Chondrosarcoma or Chondroma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Bone: Chordoma																			
		1/50	(2%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.1%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Bone: Osteoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Bone: Osteosarcoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.63%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Bone: Osteosarcoma or Osteoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		2/50	(4%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

#: Denominator is number of animals necropsied



**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

#: Denominator is number of animals necropsied

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Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 202**  
**Report Date: 11/17/2008**

Male										Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%		Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%
.....															
*Brain: Osteosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%	SD	0%
.....															
*Brain: Schwannoma Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%	SD	0%
.....															
*Clitoral/Preputial Gland: Adenoma															
		0/50	(0%)	1/50	(2%)	5/50	(10%)			3/50	(6%)	10/50	(20%)		
		0/50	(0%)	2/50	(4%)	1/50	(2%)			5/50	(10%)	8/50	(16%)	11/50	(22%)
Overall Incidence	Total	9/300	(3%)	Mean	3%	SD	3.74%		Total	37/250	(14.8%)	Mean	14.8%	SD	6.72%
.....															
*Clitoral/Preputial Gland: Carcinoma															
		1/50	(2%)	0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)		
		2/50	(4%)	0/50	(0%)	2/50	(4%)			4/50	(8%)	2/50	(4%)	3/50	(6%)
Overall Incidence	Total	5/300	(1.67%)	Mean	1.67%	SD	1.97%		Total	10/250	(4%)	Mean	4%	SD	3.16%

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

Male												Female					
#Esophagus: Fibrosarcoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Esophagus: Lipoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Eye: Amelanotic Melanoma, Benign																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Eye: Melanoma Benign																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%		Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%		
.....																	
#Eye: Melanoma Malignant																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%	SD	0%		

#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 205**  
**Report Date: 11/17/2008**

Male														Female					
#Eye:																			
Schwannoma Malignant																			
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Harderian Gland:																			
Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Harderian Gland:																			
Carcinoma or Adenoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
*Heart:																			
Schwannoma Benign																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
*Heart:																			
Schwannoma Malignant																			
		1/50	(2%)	1/50	(2%)	0/50	(0%)		1/50	(2%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.1%	Total	2/250	(0.8%)	Mean	0.8%	SD	1.1%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Page: 207  
Report Date:11/17/2008

Male												Female					
#Intestine Small: Duodenum: Leiomyoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Intestine Small: Jejunum: Carcinoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Intestine Small: Jejunum: Granular Cell Tumor Malignant																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Intestine Small: Jejunum: Leiomyoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%		
.....																	
#Intestine Small: Jejunum: Leiomyosarcoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%		

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 208**  
**Report Date: 11/17/2008**

Male										Female					
#Intestine Small: Site Unspecified: Carcinoma															
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD	0%
.....															
#Intestine Small: Site Unspecified: Carcinoma or Adenoma															
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD	0%
.....															
#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%
.....															
#Intestine Small: Site Unspecified: Leiomyoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%
.....															
#Intestine Small: Site Unspecified: Leiomyosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

Male														Female					
*Islets, Pancreatic: Adenoma																			
		1/50	(2%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	2/49	(4%)							
		7/50	(14%)	3/50	(6%)	3/50	(6%)		0/49	(0%)	0/49	(0%)	0/48	(0%)					
Overall Incidence	Total	16/299	(5.35%)	Mean	5.34%	SD	4.67%	Total	2/245	(0.82%)	Mean	0.82%	SD	1.83%					
.....																			
*Islets, Pancreatic: Carcinoma																			
		0/50	(0%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	0/49	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/49	(0%)	0/49	(0%)	0/48	(0%)					
Overall Incidence	Total	3/299	(1%)	Mean	1.01%	SD	1.1%	Total	0/245	(0%)	Mean	0%	SD	0%					
.....																			
*Islets, Pancreatic: Carcinoma or Adenoma																			
		1/50	(2%)	2/50	(4%)	2/49	(4%)		0/50	(0%)	2/49	(4%)							
		7/50	(14%)	3/50	(6%)	4/50	(8%)		0/49	(0%)	0/49	(0%)	0/48	(0%)					
Overall Incidence	Total	19/299	(6.35%)	Mean	6.35%	SD	4.27%	Total	2/245	(0.82%)	Mean	0.82%	SD	1.83%					
.....																			
*Kidney: Pelvis and Transitional Epithelium: Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/47	(0%)							
		1/50	(2%)	0/48	(0%)	0/50	(0%)		0/49	(0%)	0/48	(0%)	0/48	(0%)					
Overall Incidence	Total	1/298	(0.34%)	Mean	0.33%	SD	0.82%	Total	0/242	(0%)	Mean	0%	SD	0%					
.....																			
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/47	(0%)							
		1/50	(2%)	0/48	(0%)	0/50	(0%)		0/49	(0%)	0/48	(0%)	0/48	(0%)					
Overall Incidence	Total	1/298	(0.34%)	Mean	0.33%	SD	0.82%	Total	0/242	(0%)	Mean	0%	SD	0%					

#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

Male														Female					
*Liver: Cholangioma																			
		0/50 (0%)		1/50 (2%)		0/50 (0%)				0/50 (0%)		0/50 (0%)		0/50 (0%)					
		0/50 (0%)		0/50 (0%)		1/50 (2%)				0/50 (0%)		0/50 (0%)		0/50 (0%)					
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
*Liver: Hemangiosarcoma																			
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)		0/50 (0%)		0/50 (0%)					
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)		0/50 (0%)		0/50 (0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
*Liver: Hepatocellular Adenoma																			
		2/50 (4%)		1/50 (2%)		0/50 (0%)				0/50 (0%)		2/50 (4%)							
		1/50 (2%)		0/50 (0%)		3/50 (6%)				0/50 (0%)		0/50 (0%)		2/50 (4%)					
Overall Incidence	Total	7/300	(2.33%)	Mean	2.33%	SD	2.34%	Total	4/250	(1.6%)	Mean	1.6%	SD	2.19%					
.....																			
*Liver: Hepatocellular Carcinoma																			
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)		0/50 (0%)							
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)		0/50 (0%)		0/50 (0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
*Liver: Hepatocellular Carcinoma or Hepatoblastoma																			
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)		0/50 (0%)							
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)		0/50 (0%)		0/50 (0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					

#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 213**  
**Report Date: 11/17/2008**

		Male						Female						
*Liver:														
Hepatocellular Carcinoma or Hepatocellular Adenoma														
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	2/50	(4%)		
		1/50	(2%)	0/50	(0%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
Overall Incidence	Total	7/300	(2.33%)	Mean	2.33%	SD	2.34%	Total	4/250	(1.6%)	Mean	1.6%	SD	2.19%
.....														
*Liver:														
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma														
		2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	2/50	(4%)		
		1/50	(2%)	0/50	(0%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
Overall Incidence	Total	7/300	(2.33%)	Mean	2.33%	SD	2.34%	Total	4/250	(1.6%)	Mean	1.6%	SD	2.19%
.....														
*Lung:														
Alveolar/Bronchiolar Adenoma														
		4/50	(8%)	0/50	(0%)	1/50	(2%)		4/50	(8%)	1/50	(2%)		
		0/50	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	6/300	(2%)	Mean	2%	SD	3.1%	Total	6/250	(2.4%)	Mean	2.4%	SD	3.29%
.....														
*Lung:														
Alveolar/Bronchiolar Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%
.....														
*Lung:														
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma														
		4/50	(8%)	0/50	(0%)	1/50	(2%)		4/50	(8%)	1/50	(2%)		
		1/50	(2%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	7/300	(2.33%)	Mean	2.33%	SD	2.94%	Total	7/250	(2.8%)	Mean	2.8%	SD	3.03%
.....														

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 215**  
**Report Date: 11/17/2008**

Male														Female					
#Mammary Gland: Adenoma																			
		0/50	(0%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	1/50	(2%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		2/50	(4%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	5/250	(2%)	Mean	2%	SD	2%					
.....																			
#Mammary Gland: Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		4/50	(8%)	2/50	(4%)	4/50	(8%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	10/250	(4%)	Mean	4%	SD	4%					
.....																			
#Mammary Gland: Carcinoma or Adenoma																			
		0/50	(0%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	1/50	(2%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		6/50	(12%)	2/50	(4%)	4/50	(8%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	15/250	(6%)	Mean	6%	SD	4%					
.....																			
#Mammary Gland: Fibroadenoma																			
		2/50	(4%)	2/50	(4%)	0/50	(0%)		27/50	(54%)	29/50	(58%)							
		1/50	(2%)	3/50	(6%)	0/50	(0%)		30/50	(60%)	24/50	(48%)	28/50	(56%)					
Overall Incidence	Total	8/300	(2.67%)	Mean	2.67%	SD	2.42%	Total	138/250	(55.2%)	Mean	55.2%	SD	4.6%					
.....																			
#Mammary Gland: Fibroma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 216**  
**Report Date: 11/17/2008**

Male										Female					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma															
		2/50	(4%)	2/50	(4%)	1/50	(2%)			28/50	(56%)	30/50	(60%)		
		1/50	(2%)	3/50	(6%)	0/50	(0%)			30/50	(60%)	24/50	(48%)	28/50	(56%)
Overall Incidence	Total	9/300	(3%)	Mean	3%	SD	2.1%	Total		140/250	(56%)	Mean	56%	SD	4.9%
.....															
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma															
		2/50	(4%)	2/50	(4%)	1/50	(2%)			28/50	(56%)	30/50	(60%)		
		1/50	(2%)	3/50	(6%)	0/50	(0%)			31/50	(62%)	25/50	(50%)	28/50	(56%)
Overall Incidence	Total	9/300	(3%)	Mean	3%	SD	2.1%	Total		142/250	(56.8%)	Mean	56.8%	SD	4.6%
.....															
#Mesentery: Fibrosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		1/250	(0.4%)	Mean	0.4%	SD	0.89%
.....															
#Mesentery: Hemangiosarcoma															
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD	0%
.....															
#Mesentery: Lipoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD	0%

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied



Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 217**  
**Report Date:**11/17/2008

Male														Female					
#Mesentery:																			
Rhabdomyosarcoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Nose:																			
Adenoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
#Nose:																			
Chondroma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
#Nose:																			
Squamous Cell Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):																			
Papilloma Squamous or Papilloma																			
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	4/300	(1.33%)	Mean	1.33%	SD	1.03%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Male										Female											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma																					
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)				
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50 (0%)			
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD		0%					
.....																					
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma																					
		1/50	(2%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)				
		2/50	(4%)	0/50	(0%)	1/50	(2%)			1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50 (0%)			
Overall Incidence	Total	5/300	(1.67%)	Mean	1.67%	SD	1.51%	Total		1/250	(0.4%)	Mean	0.4%	SD		0.89%					
.....																					
#Oral Mucosa: Squamous Cell Carcinoma																					
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)				
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50 (0%)			
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD		0%					
.....																					
#Oral Mucosa: Squamous Cell Papilloma																					
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50 (0%)			
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD		0%					
.....																					
*Ovary: Granulosa Cell Tumor Benign																					
										0/50	(0%)	0/50	(0%)			0/50	(0%)				
										0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50 (0%)			
Overall Incidence	Total									0/250	(0%)	Mean	0%	SD		0%					
.....																					

#: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Male			Female			
*Ovary: Granulosa Cell Tumor Malignant						
		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)		2/50 (4%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD	1.79%	
.....						
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS						
		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)		2/50 (4%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD	1.79%	
.....						
*Ovary: Granulosa-Theca Tumor Benign						
		0/50 (0%)	1/50 (2%)			
		0/50 (0%)	0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD	0.89%	
.....						
*Ovary: Granulosa-Theca Tumor Malignant						
		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD	0%	
.....						
*Ovary: Tubulostromal Adenoma						
		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD	0%	
.....						
*: Denominator is number of animals with tissues examined microscopically						
#: Denominator is number of animals necropsied						

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 220**  
**Report Date:**11/17/2008

		Male						Female						
*Pancreas: Adenoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)		
		0/50	(0%)	1/50	(2%)	2/50	(4%)		0/49	(0%)	0/49	(0%)	0/48	(0%)
Overall Incidence	Total	3/298	(1.01%)	Mean	1%	SD	1.67%	Total	0/245	(0%)	Mean	0%	SD	0%
.....														
*Pancreas: Carcinoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/48	(0%)
Overall Incidence	Total	0/298	(0%)	Mean	0%	SD	0%	Total	0/245	(0%)	Mean	0%	SD	0%
.....														
*Pancreas: Carcinoma or Adenoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)		
		0/50	(0%)	1/50	(2%)	2/50	(4%)		0/49	(0%)	0/49	(0%)	0/48	(0%)
Overall Incidence	Total	3/298	(1.01%)	Mean	1%	SD	1.67%	Total	0/245	(0%)	Mean	0%	SD	0%
.....														
*Pancreas: Mixed Tumor Benign														
		1/50	(2%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/48	(0%)
Overall Incidence	Total	1/298	(0.34%)	Mean	0.33%	SD	0.82%	Total	0/245	(0%)	Mean	0%	SD	0%
.....														
*Pancreas: Mixed Tumor Malignant														
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)		
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/48	(0%)
Overall Incidence	Total	1/298	(0.34%)	Mean	0.33%	SD	0.82%	Total	0/245	(0%)	Mean	0%	SD	0%

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 221**  
**Report Date: 11/17/2008**

Male										Female					
*Parathyroid Gland: Adenoma															
		0/49	(0%)	1/45	(2%)	1/46	(2%)		0/47	(0%)	0/48	(0%)			
		0/49	(0%)	1/48	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)	
Overall Incidence	Total	3/287	(1.05%)	Mean	1.08%	SD	1.18%	Total	0/243	(0%)	Mean	0%	SD	0%	
.....															
#Peripheral Nerve: Schwannoma Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%	
.....															
#Peripheral Nerve: Schwannoma: Benign, Malignant, NOS															
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%	
.....															
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma															
		10/50	(20%)	10/50	(20%)	20/50	(40%)		17/50	(34%)	24/49	(49%)			
		8/50	(16%)	16/49	(33%)	13/50	(26%)		25/50	(50%)	29/48	(60%)	20/50	(40%)	
Overall Incidence	Total	77/299	(25.75%)	Mean	25.78%	SD	9.08%	Total	115/247	(46.56%)	Mean	46.68%	SD	10.13%	
.....															
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/49	(2%)			
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/48	(0%)	1/50	(2%)	
Overall Incidence	Total	0/299	(0%)	Mean	0%	SD	0%	Total	2/247	(0.81%)	Mean	0.81%	SD	1.11%	

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

#: Denominator is number of animals necropsied

**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

Male												Female					
*Prostate: Carcinoma or Adenoma																	
		0/49	(0%)	0/50	(0%)	0/50	(0%)										
		1/50	(2%)	0/50	(0%)	0/50	(0%)										
Overall Incidence	Total	1/299	(0.33%)	Mean	0.33%	SD	0.82%										
.....																	
*Salivary Glands: Sarcoma																	
		0/49	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/48	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/296	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%		SD	0%	
.....																	
*Salivary Glands: Schwannoma Malignant																	
		1/49	(2%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/48	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	1/296	(0.34%)	Mean	0.34%	SD	0.83%		Total	0/250	(0%)	Mean	0%		SD	0%	
.....																	
#Seminal Vesicle: Adenoma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)										
		0/50	(0%)	0/50	(0%)	0/50	(0%)										
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%										
.....																	
#Skeletal Muscle: Hemangioma																	
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%		Total	0/250	(0%)	Mean	0%		SD	0%	

#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Page: 224  
Report Date:11/17/2008

		Male						Female					
#Skeletal Muscle: Hemangiosarcoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD 0%
.....													
#Skeletal Muscle: Lipoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD 0%
.....													
#Skeletal Muscle: Rhabdomyosarcoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD 0%
.....													
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD 0%
.....													
#Skeletal Muscle: Sarcoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD 0%

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied



Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Male										Female											
#Skin:																					
Basal Cell Adenoma																					
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	0/250	(0%)	Mean	0%	SD	0%							
#Skin:																					
Basal Cell Adenoma or Basosquamous Tumor Benign																					
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	0/250	(0%)	Mean	0%	SD	0%							
#Skin:																					
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma																					
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	0/50	(0%)			1/50	(2%)	1/50	(2%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	2/250	(0.8%)	Mean	0.8%	SD	1.1%							
#Skin:																					
Basal Cell Carcinoma																					
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%							
#Skin:																					
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)																					
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%							

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 226**  
**Report Date: 11/17/2008**

Male										Female					
#Skin:															
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma															
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)		
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.1%	Total	2/250	(0.8%)	Mean	0.8%	SD	1.1%	
.....															
#Skin:															
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma															
		11/50	(22%)	4/50	(8%)	1/50	(2%)	3/50	(6%)	0/50	(0%)				
		2/50	(4%)	3/50	(6%)	6/50	(12%)	1/50	(2%)	2/50	(4%)	1/50	(2%)		
Overall Incidence	Total	27/300	(9%)	Mean	9%	SD	7.24%	Total	7/250	(2.8%)	Mean	2.8%	SD	2.28%	
.....															
#Skin:															
Fibroma															
		5/50	(10%)	4/50	(8%)	1/50	(2%)	3/50	(6%)	0/50	(0%)				
		5/50	(10%)	8/50	(16%)	3/50	(6%)	1/50	(2%)	1/50	(2%)	1/50	(2%)		
Overall Incidence	Total	26/300	(8.67%)	Mean	8.67%	SD	4.68%	Total	6/250	(2.4%)	Mean	2.4%	SD	2.19%	
.....															
#Skin:															
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma															
		6/50	(12%)	4/50	(8%)	4/50	(8%)	4/50	(8%)	0/50	(0%)				
		5/50	(10%)	8/50	(16%)	4/50	(8%)	3/50	(6%)	1/50	(2%)	1/50	(2%)		
Overall Incidence	Total	31/300	(10.33%)	Mean	10.33%	SD	3.2%	Total	9/250	(3.6%)	Mean	3.6%	SD	3.29%	
.....															
#Skin:															
Fibrosarcoma															
		0/50	(0%)	0/50	(0%)	2/50	(4%)	1/50	(2%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)		
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.63%	Total	2/250	(0.8%)	Mean	0.8%	SD	1.1%	

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Page: 227  
Report Date:11/17/2008

Male														Female					
#Skin:																			
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma																			
		1/50	(2%)	0/50	(0%)	3/50	(6%)		1/50	(2%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		2/50	(4%)	0/50	(0%)	1/50	(2%)					
Overall Incidence	Total	5/300	(1.67%)	Mean	1.67%	SD	2.34%	Total	4/250	(1.6%)	Mean	1.6%	SD	1.67%					
.....																			
#Skin:																			
Fibrous Histiocytoma																			
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Skin:																			
Hemangioma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Skin:																			
Hemangiosarcoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Skin:																			
Keratoacanthoma																			
		10/50	(20%)	3/50	(6%)	1/50	(2%)		3/50	(6%)	0/50	(0%)							
		2/50	(4%)	1/50	(2%)	4/50	(8%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	21/300	(7%)	Mean	7%	SD	6.78%	Total	3/250	(1.2%)	Mean	1.2%	SD	2.68%					
.....																			

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 228**  
**Report Date: 11/17/2008**

Male														Female					
#Skin:																			
Lipoma																			
		0/50	(0%)	0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)						
		1/50	(2%)	0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.1%	Total		0/250	(0%)	Mean	0%	SD	0%				
.....																			
#Skin:																			
Liposarcoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%				
.....																			
#Skin:																			
Neural Crest Tumor																			
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		1/250	(0.4%)	Mean	0.4%	SD	0.89%				
.....																			
#Skin:																			
Neural Crest Tumor, Malignant																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total		0/250	(0%)	Mean	0%	SD	0%				
.....																			
#Skin:																			
Neurofibroma or Schwannoma benign																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total		0/250	(0%)	Mean	0%	SD	0%				

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Male								Female							
#Skin:															
Neurofibrosarcoma or Schwannoma (malignant or NOS)															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%	
.....															
#Skin:															
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%	
.....															
#Skin:															
Osteosarcoma															
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%	
.....															
#Skin:															
Sarcoma															
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	2/250	(0.8%)	Mean	0.8%	SD	1.79%	
.....															
#Skin:															
Schwannoma Benign															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%	
.....															

#: Denominator is number of animals with tissues examined microscopically  
\*: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 230**  
**Report Date: 11/17/2008**

Male														Female					
#Skin:																			
Schwannoma Malignant																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Skin:																			
Squamous Cell Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)					
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Skin:																			
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	1/50	(2%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	1/50	(2%)					
Overall Incidence	Total	3/300	(1%)	Mean	1%	SD	1.67%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Skin:																			
Squamous Cell Papilloma																			
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Skin:																			
Squamous Cell Papilloma or Papilloma																			
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	2/300	(0.67%)	Mean	0.67%	SD	1.03%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Male					Female							
#Skin:												
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma												
		11/50	(22%)	3/50	(6%)	1/50	(2%)	3/50	(6%)	0/50	(0%)	
		2/50	(4%)	2/50	(4%)	6/50	(12%)	0/50	(0%)	1/50	(2%)	
Overall Incidence	Total	25/300	(8.33%)	Mean	8.33%	SD	7.53%	Total	5/250	(2%)	Mean	2%
										SD	2.45%	
#Skin:												
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma												
		11/50	(22%)	3/50	(6%)	1/50	(2%)	3/50	(6%)	0/50	(0%)	
		2/50	(4%)	1/50	(2%)	5/50	(10%)	0/50	(0%)	1/50	(2%)	
Overall Incidence	Total	23/300	(7.67%)	Mean	7.67%	SD	7.63%	Total	4/250	(1.6%)	Mean	1.6%
										SD	2.61%	
#Skin:												
Trichoepithelioma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	2/250	(0.8%)	Mean	0.8%
										SD	1.1%	
#Skin: Sebaceous Gland:												
Adenoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%
										SD	0%	
#Skin: Sebaceous Gland:												
Carcinoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%
										SD	0%	

#: Denominator is number of animals with tissues examined microscopically  
\*: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 232**  
**Report Date: 11/17/2008**

Male														Female					
#Skin: Sebaceous Gland: Carcinoma or Adenoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Spinal Cord: Astrocytoma Benign																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Spinal Cord: Astrocytoma Malignant																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Spinal Cord: Glioma Malignant																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
*Spleen: Fibrosarcoma																			
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)				
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)				
Overall Incidence	Total	0/298	(0%)	Mean	0%	SD	0%	Total	0/247	(0%)	Mean	0%	SD	0%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date:11/17/2008

Male										Female					
*Spleen: Fibrous Histiocytoma															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
		1/49	(2%)	0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	1/298	(0.34%)	Mean	0.34%	SD	0.83%		Total	0/247	(0%)	Mean	0%	SD	0%
.....															
*Spleen: Hemangioma															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	0/298	(0%)	Mean	0%	SD	0%		Total	0/247	(0%)	Mean	0%	SD	0%
.....															
*Spleen: Hemangiosarcoma															
		0/50	(0%)	1/50	(2%)	0/49	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	1/298	(0.34%)	Mean	0.33%	SD	0.82%		Total	0/247	(0%)	Mean	0%	SD	0%
.....															
*Spleen: Leiomyosarcoma															
		0/50	(0%)	1/50	(2%)	0/49	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	1/298	(0.34%)	Mean	0.33%	SD	0.82%		Total	0/247	(0%)	Mean	0%	SD	0%
.....															
*Spleen: Sarcoma															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	0/298	(0%)	Mean	0%	SD	0%		Total	0/247	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 234**  
**Report Date: 11/17/2008**

Male														Female					
#Stomach, Forestomach: Leiomyosarcoma																			
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Stomach, Forestomach: Squamous Cell Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Stomach, Forestomach: Squamous Cell Papilloma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Stomach, Glandular: Leiomyosarcoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 235**  
**Report Date: 11/17/2008**

		Male						Female					
#Stomach, Glandular:													
Lipoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD 0%
.....													
*Testes:													
Adenoma													
		45/50	(90%)	46/50	(92%)	49/50	(98%)						
		42/50	(84%)	46/50	(92%)	46/50	(92%)						
Overall Incidence	Total	274/300	(91.33%)	Mean	91.33%	SD	4.5%						
.....													
*Thymus:													
Sarcoma													
		0/48	(0%)	0/48	(0%)	0/47	(0%)	0/50	(0%)	0/46	(0%)		
		0/48	(0%)	0/48	(0%)	0/41	(0%)	0/49	(0%)	0/47	(0%)	0/50	(0%)
Overall Incidence	Total	0/280	(0%)	Mean	0%	SD	0%	Total	0/242	(0%)	Mean	0%	SD 0%
.....													
*Thymus:													
Thymoma Benign													
		0/48	(0%)	0/48	(0%)	0/47	(0%)	0/50	(0%)	0/46	(0%)		
		1/48	(2%)	0/48	(0%)	0/41	(0%)	0/49	(0%)	0/47	(0%)	0/50	(0%)
Overall Incidence	Total	1/280	(0.36%)	Mean	0.35%	SD	0.85%	Total	0/242	(0%)	Mean	0%	SD 0%
.....													
*Thymus:													
Thymoma Malignant													
		0/48	(0%)	0/48	(0%)	0/47	(0%)	0/50	(0%)	0/46	(0%)		
		0/48	(0%)	0/48	(0%)	0/41	(0%)	0/49	(0%)	0/47	(0%)	0/50	(0%)
Overall Incidence	Total	0/280	(0%)	Mean	0%	SD	0%	Total	0/242	(0%)	Mean	0%	SD 0%

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Page: 236  
Report Date:11/17/2008

		Male						Female						
*Thymus:														
Thymoma: Benign, Malignant, NOS														
		0/48	(0%)	0/48	(0%)	0/47	(0%)	0/50	(0%)	0/46	(0%)			
		1/48	(2%)	0/48	(0%)	0/41	(0%)	0/49	(0%)	0/47	(0%)	0/50	(0%)	
Overall Incidence	Total	1/280	(0.36%)	Mean	0.35%	SD	0.85%	Total	0/242	(0%)	Mean	0%	SD	0%
.....														
*Thyroid Gland: C-Cell:														
Adenoma														
		10/50	(20%)	5/50	(10%)	6/50	(12%)	4/50	(8%)	3/49	(6%)			
		7/50	(14%)	11/47	(23%)	5/48	(10%)	4/50	(8%)	10/47	(21%)	2/47	(4%)	
Overall Incidence	Total	44/295	(14.92%)	Mean	14.97%	SD	5.51%	Total	23/243	(9.47%)	Mean	9.53%	SD	6.75%
.....														
*Thyroid Gland: C-Cell:														
Carcinoma														
		1/50	(2%)	4/50	(8%)	1/50	(2%)	0/50	(0%)	1/49	(2%)			
		1/50	(2%)	0/47	(0%)	1/48	(2%)	1/50	(2%)	1/47	(2%)	0/47	(0%)	
Overall Incidence	Total	8/295	(2.71%)	Mean	2.68%	SD	2.73%	Total	3/243	(1.23%)	Mean	1.23%	SD	1.13%
.....														
*Thyroid Gland: C-Cell:														
Carcinoma or Adenoma														
		11/50	(22%)	9/50	(18%)	7/50	(14%)	4/50	(8%)	4/49	(8%)			
		8/50	(16%)	11/47	(23%)	6/48	(13%)	5/50	(10%)	11/47	(23%)	2/47	(4%)	
Overall Incidence	Total	52/295	(17.63%)	Mean	17.65%	SD	4.35%	Total	26/243	(10.7%)	Mean	10.76%	SD	7.37%
.....														
*Thyroid Gland: Follicular Cell:														
Adenoma														
		2/50	(4%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/49	(0%)			
		0/50	(0%)	0/47	(0%)	0/48	(0%)	0/50	(0%)	2/47	(4%)	0/47	(0%)	
Overall Incidence	Total	4/295	(1.36%)	Mean	1.33%	SD	2.07%	Total	2/243	(0.82%)	Mean	0.85%	SD	1.9%

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 237**  
**Report Date: 11/17/2008**

Male														Female					
*Thyroid Gland: Follicular Cell: Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)							
		0/50	(0%)	0/47	(0%)	0/48	(0%)		0/50	(0%)	0/47	(0%)	1/47	(2%)					
Overall Incidence	Total	0/295	(0%)	Mean	0%	SD	0%	Total	1/243	(0.41%)	Mean	0.43%	SD	0.95%					
.....																			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma																			
		2/50	(4%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/49	(0%)							
		0/50	(0%)	0/47	(0%)	0/48	(0%)		0/50	(0%)	2/47	(4%)	1/47	(2%)					
Overall Incidence	Total	4/295	(1.36%)	Mean	1.33%	SD	2.07%	Total	3/243	(1.23%)	Mean	1.28%	SD	1.9%					
.....																			
#Tissue NOS: Lipoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Tissue NOS: Paraganglioma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)					
Overall Incidence	Total	1/300	(0.33%)	Mean	0.33%	SD	0.82%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Tissue NOS: Schwannoma Malignant																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)					
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 238**  
**Report Date: 11/17/2008**

Male														Female					
#Tongue:																			
Squamous Cell Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Tongue:																			
Squamous Cell Carcinoma or Papilloma Squamous																			
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	4/300	(1.33%)	Mean	1.33%	SD	1.03%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Tongue:																			
Squamous Cell Papilloma																			
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	4/300	(1.33%)	Mean	1.33%	SD	1.03%	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					
.....																			
#Tooth:																			
Adamantinoma Malignant																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					
.....																			
#Tooth:																			
Odontoma																			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/300	(0%)	Mean	0%	SD	0%	Total	0/250	(0%)	Mean	0%	SD	0%					

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied

Version: Nov2008  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ORAL**  
**Vehicle: FEED**

**Page: 239**  
**Report Date: 11/17/2008**

Male														Female					
*Urinary Bladder: Carcinoma																			
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)	0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	0/298	(0%)	Mean	0%	SD	0%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
*Urinary Bladder: Carcinoma or Papilloma																			
		0/50	(0%)	0/50	(0%)	1/49	(2%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)	0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	1/298	(0.34%)	Mean	0.34%	SD	0.83%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
*Urinary Bladder: Leiomyosarcoma																			
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)	0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	0/298	(0%)	Mean	0%	SD	0%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
*Urinary Bladder: Papilloma																			
		0/50	(0%)	0/50	(0%)	1/49	(2%)			0/50	(0%)	0/50	(0%)						
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)	0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	1/298	(0.34%)	Mean	0.34%	SD	0.83%	Total	0/249	(0%)	Mean	0%	SD	0%					
.....																			
#Uterus: Adenoma																			
										0/50	(0%)	0/50	(0%)						
										0/50	(0%)	0/50	(0%)	1/50	(2%)				
Overall Incidence								Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%					

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: Nov2008  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

Toxicology Data Management System  
Tumor Incidence for Selected Control Animal Groups  
Route: ORAL  
Vehicle: FEED

Male			Female			
#Uterus: Carcinoma						
			0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD 0%
.....						
#Uterus: Deciduoma Benign						
			0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD 0%
.....						
#Uterus: Hemangioma						
			0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD 0%
.....						
#Uterus: Hemangiosarcoma						
			0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD 0%
.....						
#Uterus: Leiomyoma						
			0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD 0%
.....						

\*: Denominator is number of animals with tissues examined microscopically  
#: Denominator is number of animals necropsied



**Length of Study:** CHRONIC

### Tumor Incidence for Selected Control Animal Groups

**Vehicle: FEED**

Report Date:11/17/2008

		Male		Female			
#Uterus:							
Leiomyosarcoma							
			0/50 (0%)		0/50 (0%)		
			1/50 (2%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%
.....							
#Uterus:							
Polyp Stromal							
			6/50 (12%)		10/50 (20%)		
			14/50 (28%)		16/50 (32%)		10/50 (20%)
Overall Incidence	Total	56/250	(22.4%)	Mean	22.4%	SD	7.8%
.....							
#Uterus:							
Sarcoma Stromal							
			0/50 (0%)		0/50 (0%)		
			0/50 (0%)		1/50 (2%)		0/50 (0%)
Overall Incidence	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%
.....							
#Uterus:							
Sarcoma Stromal or Polyp Stromal							
			6/50 (12%)		10/50 (20%)		
			14/50 (28%)		17/50 (34%)		10/50 (20%)
Overall Incidence	Total	57/250	(22.8%)	Mean	22.8%	SD	8.44%
.....							
#Uterus:							
Schwannoma Malignant							
			0/50 (0%)		0/50 (0%)		
			0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

**Version:** Nov2008

**Contract/Lab:** All Laboratories

**Species:** RATS

Strain: F344

**Length of Study:** CHRONIC

## Toxicology Data Management System

### Tumor Incidence for Selected Control Animal Groups

Route: ORAL

**Vehicle: FEED**

Page: 242

Report Date:11/17/2008

Male										Female					
#Vagina: Polyp															
		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)	
Overall Incidence		Total		0/250 (0%)		Mean		0%		SD		0%			
.....															
#Vagina: Sarcoma															
		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)	
Overall Incidence		Total		0/250 (0%)		Mean		0%		SD		0%			
.....															
#Zymbal's Gland: Adenoma															
		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)		0/50 (0%)	
Overall Incidence		Total		0/300 (0%)		Mean		0%		SD		0%			
.....															
#Zymbal's Gland: Carcinoma															
		0/50 (0%)		0/50 (0%)		1/50 (2%)		0/50 (0%)		1/50 (2%)		0/50 (0%)		0/50 (0%)	
Overall Incidence		Total		4/300 (1.33%)		Mean		1.33%		SD		2.42%			
.....															
#Zymbal's Gland: Carcinoma or Adenoma															
		0/50 (0%)		0/50 (0%)		1/50 (2%)		0/50 (0%)		1/50 (2%)		0/50 (0%)		0/50 (0%)	
Overall Incidence		Total		4/300 (1.33%)		Mean		1.33%		SD		2.42%			

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied